



Experimental Tissue Resource (ETR)

Research Tissue
work-flow

Delia Tifrea

9-19-19

Experimental Tissue Resource (ETR)

- ▶ Shared Resource of Chao Family Comprehensive Cancer Center



- ▶ UCI IRB Approved: 08-22-2018 | CPA# 24665 | HS# 2012-8716

- Honest broker status
- Facilitates and track usage of tissue for research

Contact info:

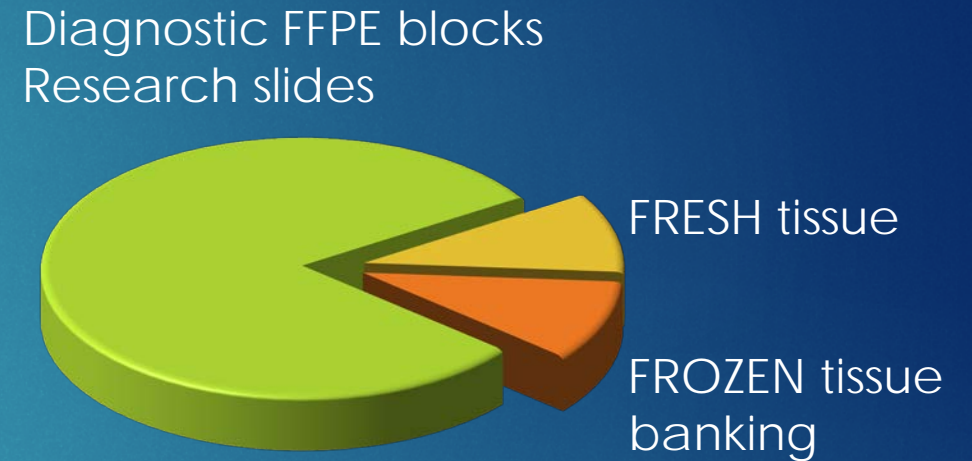
Biorepository Manager: [Delia Tifrea, PhD, MBA](#)
Phone: 714-872-1093
Fax: 714-456-5873
email: dtifrea@uci.edu

Research Histology Specialist: [Jeffrey Kim](#)
Phone: 714-456-3389
Fax: 714-456-3637
email: jbkim@uci.edu

Director: [Robert Edwards, MD, PhD](#)
Phone: 949-824-8576, 714-456-6141
email: redwards@uci.edu

ETR SERVICES

- ▶ Archival FFPE blocks and slides
- ▶ Archived Frozen Tissue
- ▶ Fresh Tissue by FNA/ Biopsy/ Surgical
- ▶ IHC
- ▶ Borrowing of Diagnostic Slides for eligibility confirmation



Standard Operating Procedures

- ▶ Per HRP Policy 15 and the UCIMC Anatomical Pathology/Surgical Pathology - Procedure Number: S-23: all specimens removed from clinic or the operating room must be sent to UCIMC Pathology for review and documentation by a pathologist.
- ▶ **Only remnants are to be used for research;** a remnant is defined as tissue not needed for diagnosis.
- ▶ A faculty pathologist is the only physician authorized to determine the release of tissue for research.
- ▶ The determination cannot be made by surgeons or other physicians.
- ▶ **Pathology has to be notified of all tissue collections for research.**

Exempt Specimens

- ▶ UCI Department of Pathology and Laboratory Medicine is **charged with the management of all** non-dermal tissues and fluids and prosthetics derived from procedures at UCI
- ▶ Usually not submitted to Pathology for processing.
- ▶ Exempt tissue
 - defined as Specimen that don't need meaningful examination-
 - cataract, orthopedic appliance, newborn foreskin, bone from degenerative joints, bunions, spinal procedures, or portion of and removed only to enhance operative exposure; menisci, articular cartilage and blood clots.
 - Radioactive medical devices & sources (managed by EH&S)
 - Traumatic amputations where examination for either medico/legal reasons is not deemed necessary.
 - Foreign bodies (for example, bullets)
 - Placentas that are grossly normal as determined by the delivering gynecologist
 - Tonsil and adenoids of patients under age 17.
 - Stones of visceral organs.

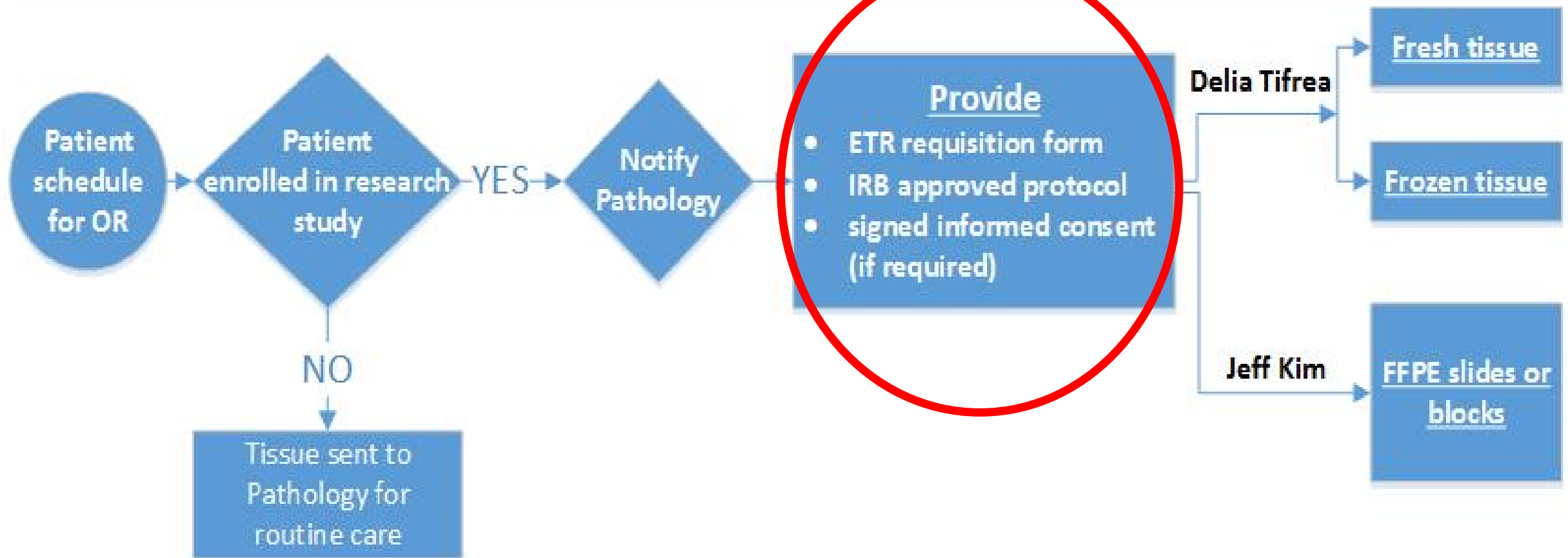
Research Human Tissue can be obtained at UCI in 2 scenarios:

1. Confirm that the specimens will be obtained from the ETR, Pathology

or

2. Obtain confirmation from a UCIMC Pathologist (ETR) that the proposed **exempt specimen*** may be collected directly from the unit/ department/ OR.

Research tissue Flow Process



Fresh Tissue Procurement

- ▶ Urgency due to short viability of the tissue or last minute obtained informed consent
- ▶ Must provide all 3 documents prior to tissue collection from Pathology:
 1. IRB approval + narrative of that protocol: type of tissue, quantity approved for, conditions
 2. Patient's signed informed consent (UCOP Policy No. 9420 -24h) –statements in writing, text or picture
 3. ETR requisition form

E-mail: dtifrea@uci.edu

Call/ text: 714-872-1093

Patient Name / MRN / study

Person collecting the tissue: **Phone number!**

Research-only Biopsy

- ▶ Must notify Pathology!
- ▶ Not exempt from Pathology, even if approved to be collected directly from the OR

E-mail: dtifrea@uci.edu
Call/ text: 714-872-1093
Patient Name / MRN / study
Person collecting the tissue

Diagnostic Slides for Research

- ▶ H&Es, special cytochemical or IHC Stains
- ▶ Six week loan out.
 - ▶ 24-48 hours turn around
- ▶ Must provide 2 documents:
 1. IRB approval + narrative of that protocol: type of slides, quantity approved for, conditions
 2. Patient's signed informed consent for a specific study

E-mail: dtifrea@uci.edu

Call/ text: 714-872-1093

Patient Name / MRN / study

Person collecting the tissue + Destination

FFPE Tissue Procurement

- ▶ Must provide all 3 documents:
 1. IRB approval + narrative of that protocol: type of tissue, quantity approved for, conditions
 2. Patient's signed informed consent for a specific study
 3. ETR Requisition form

Contact: [Jeffrey Kim](#)
Phone: 714-456-3389
Fax: 714-456-3637
email: jbkim@uci.edu

Experimental Tissue Resource (ETR)

Department of Pathology & Laboratory Medicine
UNIVERSITY of CALIFORNIA, IRVINE • SCHOOL OF MEDICINE

Department of Pathology > Human Tissue Procurement and Biorepository

TISSUE PROCUREMENT AND BIOREPOSITORY

Access to Tissue

The Tissue Biorepository is a component of the Research Core Facilities of the Department of Pathology & Laboratory Medicine. Its mission is to support the human tissue needs of UC Irvine Health research protocols and associated institutions.

Other services of the Research Core include:

- Immunohistochemistry
- Special staining
- Nucleic acid purification and diagnostics
- Laser capture microdissection
- Other services.

The biorepository provides fresh surgical specimens of many kinds that are in excess of clinical needs. These tissues can be provided as frozen specimens or maintained as special media for support of tissue culture and other time-sensitive protocols. Tissue is provided to investigators by coordination with the biorepository manager (see "Inquiries" below).

Disposition of all human tissue samples are the responsibility of the Department of Pathology. Tissue may not be taken directly from operating rooms or any clinic without approval by a pathologist, who must inspect the tissue and determine how much (if any) is not needed for diagnostic purposes and can be spared for a research project. An exception may be permitted for tissues that are not normally examined, such as normal placentas, discarded normal skin or other tissues from purely cosmetic procedures without underlying or history of disease. A list of these exempted tissues is available in the UC Irvine Health Hospital Rules and Regulations.

Archival formalin-fixed, paraffin embedded (FFPE) tissue is also available. Biorepository clients can request the selection, retrieval, sectioning and staining of human tissue sections from departmental archives spanning 1993 to the present. Depending on the level of IRB approval obtained, clients may also obtain associated clinical outcome data. Archival tissues may be used for preparing slides of various thicknesses, RNA and DNA preparation, for immunohistochemistry, special staining, genomics analyses and many other services of the research core facilities. Those interested in making tissue microarrays should inquire (see "Inquiries" below). Whole tissue blocks held for less than 10 years will not be released, with the exception of a requirement by a therapeutic clinical trial where examination of the block by an outside laboratory is required for inclusion of the subject into the trial.

The biorepository maintains a retrospective collection of frozen tissues available for research (see "Inquiries" below). In addition, the biorepository cooperates in the development of specialized collections, obtaining informed consents, obtaining a wide range of clinical follow-up information and many other aspects of research protocols.

Recharges

A signed receipt prepared by the biorepository manager for all tissue provided to researchers must be obtained. The availability of tissue is notified to research as soon as the biorepository manager makes it available. All fresh tissues are recharged at the rate of \$25 per case. Archival tissue procurement and histologic services are billed separately; recharge rates and the requisition form are available here as a Word document or pdf. Researchers developing protocols for the use of Biorepository tissue are strongly encouraged to include costs in preparing budgets for grant and other support.

UC Irvine Health Internal Review Board

The biorepository is required to maintain a copy of the entire active IRB approval (not just the approval letter) for all protocols requiring biorepository services. All protocols citing the use of human tissue must have either a current IRB approved protocol or a written exemption from the IRB. The latter form is also required for "exempt tissues," above.

Inquiries

Anne Sawyers, biorepository manager, 714.456.8975

ETR website: <http://www.pathology.uci.edu/research-services-core-facility.asp>

Experimental Tissue Resource (ETR)



The screenshot shows the website for the Department of Pathology & Laboratory Medicine at the University of California, Irvine. The page is titled "RESEARCH SERVICES" and provides information about the Experimental Tissue Resource (ETR). The left sidebar contains a navigation menu with links to HOME, ABOUT US, LABORATORY SERVICES, FACULTY, RESEARCH, EDUCATION, GRAND ROUNDS, CLINICAL TRIALS, PHILANTHROPY, EMPLOYMENT, CONTACT US, RELATED LINKS, and RESOURCES. The main content area includes a search bar, a breadcrumb trail "Department of Pathology > Research Services Core Facility", and a detailed description of the ETR. The ETR is described as a group of facilities and personnel that serve UCI's research community with anatomic and clinical laboratory services, instrumentation, and professional interpretive services. It handles requests for archival human tissue samples and non-human histology services purely for research purposes, as well as requests for prospective collection of fresh or flash-frozen human tissues for research, clinical trials, or tissue banking, and archival tissue requests for patient care-related cases. The personnel listed include: Director: Robert Edwards, MD, PhD (Phone: 949-824-8576, 714-456-6141; email: redwards@uci.edu); Biorepository Manager: Delia Tifrea (Phone: 714-872-1093; email: dtifrea@uci.edu); Basic Research Services Manager: Delia Tifrea (Phone: 714-872-1093; email: dtifrea@uci.edu); Research Histology Specialist: Jeffrey Kim (Phone: 714-456-3389; Fax: 714-456-3637; email: jbkim@uci.edu); and Finance Manager: Rick Koser (Phone: 949-824-2661). At the bottom, there are two buttons: "Basic Research Services »" and "Clinical Research, Clinical Trials, and Patient Care Tissue Services »".

DEPARTMENT OF PATHOLOGY & LABORATORY MEDICINE
UNIVERSITY of CALIFORNIA, IRVINE • SCHOOL OF MEDICINE

Search Site UCI.edu People

HOME Department of Pathology > Research Services Core Facility

ABOUT US

LABORATORY SERVICES >

FACULTY

RESEARCH >

EDUCATION >

GRAND ROUNDS

CLINICAL TRIALS

PHILANTHROPY

EMPLOYMENT

CONTACT US

RELATED LINKS >

RESOURCES >

RESEARCH SERVICES

Research Services are a group of facilities and personnel that serve UCI's research community with anatomic and clinical laboratory services, instrumentation, and professional interpretive services that support research efforts in the basic, translational, and clinical trials research spaces. Our Pathologists support research efforts in the School of Medicine, the Ayala School of Biological Sciences, the Samueli School of Engineering, Pharmaceutical Sciences and the School of Public Health.

The portal for research services is the Experimental Tissue Resource (ETR), which is co-administered by the Cancer Center and Pathology, within the Department of Pathology. The ETR handles requests for archival human tissue samples and non-human histology services purely for research purposes, as well as requests for prospective collection of fresh or flash-frozen human tissues for research, clinical trials, or tissue banking, and archival tissue requests for patient care-related cases.

Personnel:

Director: [Robert Edwards, MD, PhD](#)
Phone: 949-824-8576, 714-456-6141
email: redwards@uci.edu

Biorepository Manager: [Delia Tifrea](#)
Phone: 714-872-1093
email: dtifrea@uci.edu

Basic Research Services Manager: [Delia Tifrea](#)
Phone: 714-872-1093
email: dtifrea@uci.edu

Research Histology Specialist: [Jeffrey Kim](#)
Phone: 714-456-3389
Fax: 714-456-3637
email: jbkim@uci.edu

Finance Manager: [Rick Koser](#)
Phone: 949-824-2661

Basic Research Services »

Clinical Research, Clinical Trials, and Patient Care Tissue Services »

ETR website: <http://www.pathology.uci.edu/research-services-core-facility.asp>

ETR Requisition Form

Received Date: _____ Sent Out Date: _____ Reference No.: _____
Specimen No.: _____

RESEARCH HISTOLOGY and BIO-REPOSITORY SERVICES REQUEST FORM

UCI DEPARTMENT OF PATHOLOGY — EXPERIMENTAL TISSUE RESOURCE

USER INFORMATION (ALL sections must be filled in):

Today's Date: _____ Department: _____ Recharge / Account No: _____

Principal Investigator Name: _____ PI's E-mail: _____
CRC or Lab Manager Name: _____ CRC or Manager E-mail: _____
Fiscal Officer Name: _____ CRC or Manager Phone No: _____
Fiscal Officer Phone No.: _____ Fiscal Officer E-mail: _____
End User or Contact Person: _____ End User's E-mail: _____
End User Phone No.: _____

Protocol No / Title of Study: _____

COMPLIANCE INFORMATION (services will NOT be performed without this information):

Do requested services involve use of human tissue? YES NO
• If YES, attach IRB approval letter. If previously attached, list IRB No. _____

Do requested services involve use of vertebrate animal tissue? YES NO
• If YES, attach IACUC approval letter. If previously attached, list IACUC No. _____

Indicate end use of this service (check the one that most applies): Research Clinical Teaching

Check here if this is a "RUSH" clinical trials sample (turnaround time is 1-3 calendar days). Please indicate desired turnaround time? _____ day.

Required Authorization Signature (if pre-authorization is required by PI or Department):
By signing below, you certify that the above information is current and correct, and approve payment against the recharge account or agree to pay for services requested. Services cannot be provided without the signature of the PI or the FO.

Principal Investigator OR Recharge Account Fiscal Officer

Please provide here the Recharge account number specific for the protocol number

Study HS #
Patient's name/
MRN

If your Exempt Review letter states that this does not qualify as a human research and does not need IRB Approval: Click NO

ETR Requisition Form

<u>Histology Service Requested</u>	<u>Quantity</u>	<u>Unit Cost</u>	<u>Total Cost</u>
<u>Request FFPE Human Tissue Block from Pathology Department Archive</u>			
<input type="checkbox"/> A Archive search by diagnosis (up to 10 blocks) §	NA		
<input type="checkbox"/> B Archive search for each additional block or by patient identifier, per block*		\$ 3.00	\$ 0.00
<u>Process a Clinical Research Specimen in Pathology Dept., WITH Adequacy check</u>			
<input type="checkbox"/> C Pathologist Assessment of tumor presence and sufficiency for assessment		\$ 50.00	\$ 0.00
<u>Process User Supplied Samples without Pathologist Review</u>			
<input type="checkbox"/> D Trim, process, orient, and paraffin embed fixed tissue		\$ 7.00	\$ 0.00
<input type="checkbox"/> D1 All of the above, with one H&E (per block)		\$ 13.00	\$ 0.00
<input type="checkbox"/> D2 Batch rate (minimum of 10 samples), with one H&E (per block)		\$ 11.00	\$ 0.00
<input type="checkbox"/> E Trim and orient frozen tissue in OCT, user supplied frozen specimen		\$ 10.00	\$ 0.00
<input type="checkbox"/> F Cut per frozen specimen provided from Bio-repository		\$ 20.00	\$ 0.00
<input type="checkbox"/> G Decal Bone specimen		\$ 10.00	\$ 0.00

Clear Form

Department of Pathology and Laboratory Medicine Form S-65 ver. 10/15/2017
UC Irvine Medical Center

Please provide here the number cassettes



RESEARCH HISTOLOGY and BIO-REPOSITORY SERVICES REQUEST FORM

<u>Histology Service Requested</u>	<u>Quantity</u>	<u>Unit Cost</u>	<u>Total Cost</u>
<u>Cut Unstained Slide from Tissue Blocks</u>			
<input type="checkbox"/> H Cut first slide (1 or 2 sections/slide, on Superfrost+ slide) #/slide		\$ 4.00	\$ 0.00
<input type="checkbox"/> H1 Re-cut additional		\$ 3.00	\$ 0.00
<input type="checkbox"/> H2 Cut tissue into		\$ 4.00	\$ 0.00
<input type="checkbox"/> I Cut first frozen section (1 or 2 sections/slide, on Superfrost+ slide) #/slide		\$ 6.00	\$ 0.00

Please provide here the number of slides



ETR Requisition Form

Bio-Repository Service Requested (UCI 12-11 IRB#2012-8716)

Request Human Tissue Specimens, either Fresh or Frozen - Clinical Trials ONLY

Is the sample from Research Only Biopsy? YES NO

Cytopathology Adequacy Check Required during the Biopsy? YES NO

Type of report required

- Full Ascertainment

	Quantity	Unit Cost	Total Cost
<input type="checkbox"/> Q Fresh tissue / Frozen Inventory / OCT embedded frozen tissue, per specimen			
<input type="checkbox"/>		\$ 25.00	\$ 0.00
<input type="checkbox"/>		\$ 25.00	\$ 0.00

Request an Existing FFPE Block to be "Cored" (e.g., - for TMA)

R Case and Block Number(s): Core's Diameter (1, 2, 3mm): \$ 25.00 \$ 0.00

<input type="checkbox"/> UCI investigators / Subtotal			\$ 0.00
<input type="checkbox"/> Outside For-profit/Non-profit Total	250% of subtotal		\$ 0.00

For orders not picked-up at UCI or UCIMC:

Shipping (packaging charge \$5 dry, \$25 dry ice, or TBD) (your FedEx #)

You can use this space to identify this particular tissue for your records: example: date

Please mark the quantity/ or number of pieces/ any other measure that describes the tissue you received

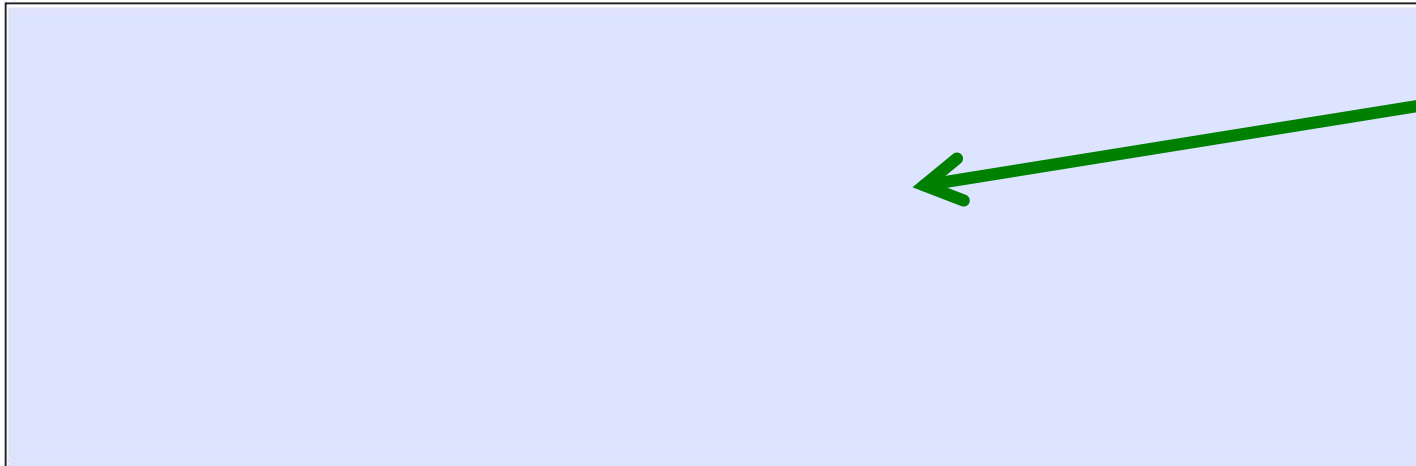
Sponsored trial are Outside / for profit

ETR Requisition Form

RESEARCH HISTOLOGY and BIO-REPOSITORY SERVICES REQUEST FORM

If there are more specific instructions, please describes below, and copy your specific instructions with the cover email or fax when submitting this form.

- If special embedding is required, please state exact orientation of the tissue.
- For sections, please include how they should be cut, number of microns between cuts, and whether you want the block completely cut through.
- For electron microscopy, explain what structures need to be photographed and at what magnification.



Please provide here any special instructions



Picking up your bio-specimen

- ▶ Only a certified person can pick up sample (for clinical trials, collecting samples with PHI: their name has to be on the approved IRB narrative)
 - ▶ Wait to be notified that tissue is ready to be picked up
 - ▶ Please bring a secondary container for transport
 - ▶ Find tissue in the 4°C fridge: RESEARCH TRAY
 - ▶ Before you leave, please Sign-out form (table by the exit)
 - ▶ Date; Time; Pick up person; Signature of pick up person; Tissue type and quantity; Study ID or IRB ID; Surgipath or MRN

Picking up your bio-specimen

- Refer all research questions to ETR personal by call / text/ E-mail
- Please do not call Pathology Grossing room or OR repeatedly. Wait to be notified of tissue availability
- Please do not impede the Grossing room work-flow process for diagnostic
- All tissue collections at UCI need to be accounted for.

Questions?

- Thank you !